

510(K) SUMMARY – K 081603
(as required by 807.92(c))

Regulatory Correspondent

AJW Technology Consultants Inc.
962 Allegro Lane
Apollo Beach, FL 33572

JUL 24 2009

Submitter of 510(k):

HeartForce Medical, Inc
Suite 200-100 Park Royal South
Vancouver, BC V7T 1A2
Canada
Phone: (604)-566-8200
Fax: (604)-566-8201

Contact Person:

Adrian Somers

Date of Summary:

07/21/09

Trade/Proprietary Name:

dBG Digital Ballistocardiograph

Classification Name:

Ballistocardiograph

Product Code:

DXR

Intended Use:

The dBG 300 records vibrational waveforms produced by the hearts contractions and transmitted to the chest wall. The dBG 300 may be used as a tool to measure the timing of the events in the cardiac cycle.

Device Description:

The Heart Force Ballistocardiograph senses and analyzes the mechanical movement of the heart. This is accomplished with 2 or 3 standard ECG electrodes for the ECG signal and with a suitable miniature electronic accelerometer for the mechanical motion.

Predicate Device:

K910994 Modified Seismocardiograph - Seismed Instruments, Inc

Substantial Equivalence:

Heart Force claims the proposed device to be substantially equivalent to the previously cleared device by FDA in K910994. Heart Force claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, physical and operational specifications as compared to the predicate device.

In addition to bench data, the submittal includes clinical data collected to compare the subjects device's finding of the times of occurrence of cardiac events such as aortic valve opening or closing with that of an echocardiograph.

Features and Functions	Seismed SCG- 2000 Seismocardiograph	Heartforce dBG 300
DBG Software		
<i>Record Management and Platform</i>		
Tests Stored as individual files	Yes	Yes
Save Test	Yes	Yes
File Retrieval	From 3.5" floppy disk	From Hard Drive or external drive
Operating System	Proprietary	Windows XP, Windows Vista
PC-Based Software	No, Proprietary software on proprietary operating	Yes
Printing	Yes	Yes
Networked	No	No
Modem Data Transfer	Yes	No
Security		
Printer	Yes	No (may use standard Windows Printers)
<i>Patient Demographics</i>		
Patient Name	Yes	Yes
Gender	No	Yes
Date of Birth	No	Yes
Comments	Yes	Yes
Patient ID	Yes	No
<i>Physician Demographics (for Modem Transfer)</i>	Yes	Yes
<i>Recording Test</i>		
ECG - BCG Synchronized Stacked Display	Yes	Yes (ECG & 3 Axis X, Y, Z BCG)
Rhythm Strip	No	Yes
ECG	3 Lead	No, Single Lead Rhythm Strip
X Axis BCG	No	Yes
Y Axis BCG	No	Yes
Z Axis BCG	Yes	Yes
Preset Recording time	30 Secs	User Configurable 10 secs, 30 secs, 60 Secs
Pre Exercise Test	Yes	Yes
Post Exercise Test	Yes	Yes
Recovery Test	Yes	No
<i>ECG - BCG Review</i>		
Waveform Markers	No	Yes, User Applies Markers for ACC recognized waves (Mitral Valve Close, J, Mitral Valve Open, Aortic Value Open, Aortic Valve Close, Early Diastole)
Scroll BCG	Yes	Yes
Zoom BCG	No	Yes
Measurements	No	Yes
Signal Averaging	Yes	Yes

Reports		
BCG Complex	Yes	Yes
MVC to AVO: Shows the Mitral Valve Close to Aortic Valve Open time	No	Yes
AVO to AVC: Shows the systolic ejection period	No	Yes
AVC to MVC: Shows the isovolumic	No	Yes
MVO to ED: Shows the Mitral Valve Open to Early Diastole time	No	Yes
AVO: Aortic Valve Opening	No	Yes
MVO: Mitral Valve Opening	No	Yes
dBG Hardware		
Portable Unit	Semi Portable Beside Unit	Portable hand held unit
Battery Power	No	Yes
Tri-axial Accelerometer	No (2 Axis)	Yes
Detachable Patient Cable (ECG, BCG)	Yes	Yes
ECG Lead Wires	Yes	No (ECG adhesive patches applied to sensor and patient)
Data Transmission	Built in unit	Wireless Bluetooth transmission from dBG 300 device to dBG Software on a PC
Handheld unit	No, Cart based system portable on wheels	Yes, small handheld unit



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HeartForce Medical, Inc.
c/o Mr. Arthur Ward
AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

JUL 24 2009

Re: K081603

Trade/Device Name: dBG 300 Digital Ballistocardiograph
Regulatory Number: 21 CFR 870.2320
Regulation Name: Ballistocardiograph
Regulatory Class: Class II (Two)
Product Code: DXR, DSB
Dated: May 27, 2009
Received: May 28, 2009

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

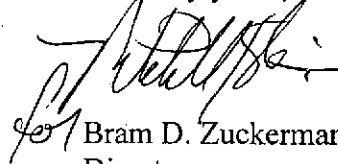
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: K 081603

Device Name: dBG 300 Digital Ballistocardiograph

Indications for Use:

The dBG 300 records vibrational waveforms produced by the hearts contractions and transmitted to the chest wall. The dBG 300 may be used as a tool to measure the timing of the events in the cardiac cycle.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

7/24/09
Division of Cardiovascular Devices

510(k) Number K081603